

shall issue approvals for other respiratory protective devices not specifically described in this part subject to such additional requirements as may be imposed in accordance with § 84.63(c).

**§ 84.61 General construction requirements.**

(a) Respirators will not be accepted by the Institute for examination, inspection and testing unless they are designed on sound engineering and scientific principles, constructed of suitable materials and evidence good workmanship.

(b) Respirator components which come into contact with the wearer's skin shall be made of nonirritating materials.

(c) Components replaced during or after use shall be constructed of materials which will not be damaged by normal handling.

(d) Mouthpieces, hoods, helmets, and facepieces, except those employed in single-use respirators, shall be constructed of materials which will withstand repeated disinfection as recommended by the applicant in his instructions for use of the device.

**§ 84.62 Component parts; minimum requirements.**

(a) The component parts of each respirator shall be:

(1) Designed, constructed, and fitted to insure against creation of any hazard to the wearer;

(2) Assembled to permit easy access for inspection and repair of functional parts; and

(3) Assembled to permit easy access to parts which require periodic cleaning and disinfecting.

(b) Replacement parts shall be designed and constructed to permit easy installation and to maintain the effectiveness of the respirator.

**§ 84.63 Test requirements; general.**

(a) Each respirator and respirator component shall when tested by the applicant and by the Institute, and meet the applicable requirements set forth in subparts H through L of this part.

(b) Where a combination respirator is assembled from two or more types of respirators, as described in this part,

each of the individual respirator types which have been combined shall, as applicable, meet the minimum requirements for such respirators set forth in subparts H through L of this part, and such combination respirators, except as specified in § 84.70(b)(2), will be classified by the type of respirator in the combination which provides the least protection to the user.

(c) In addition to the minimum requirements set forth in subparts H through L of this part, the Institute reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

(d) Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

**§ 84.64 Pretesting by applicant; approval of test methods.**

(a) Prior to making or filing any application for approval or modification of approval, the applicant shall conduct, or cause to be conducted, examinations, inspections, and tests of respirator performance which are equal to or exceed the severity of those prescribed in this part.

(b) With the application, the applicant shall provide a statement to the Institute showing the types and results of the examinations, inspections, and tests required under paragraph (a) of this section and state that the respirator meets the minimum requirements of subparts H through L of this part, as applicable. Complete examination, inspection, and test data shall be retained on file by the applicant and be submitted, upon request, to the Institute.

(c) The Institute may, upon written request by the applicant, provide drawings and descriptions of its test equipment and otherwise assist the applicant in establishing a test laboratory

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or securing the services of a testing agency.

(d) No approval will be issued until the Institute has validated the applicant's test results.

### **§ 84.65 Conduct of examinations, inspections, and tests by the Institute; assistance by applicant; observers; recorded data; public demonstrations.**

(a) All examinations, inspections, and tests conducted pursuant to subparts H through L of this part will be under the sole direction and control of the Institute.

(b) The Institute may, as a condition of approval, require the assistance of the applicant or agents of the applicant during the assembly, disassembly, or preparation of any respirator or respirator component prior to testing or in the operation of such equipment during testing.

(c) Only Institute personnel, persons assisting the Institute pursuant to paragraph (b) of this section, and such other persons as are requested by the Institute or the applicant to be observers, shall be present during any examination, inspection, or test conducted prior to the issuance of an approval by the Institute for the equipment under consideration.

(d) The Institute shall hold as confidential any analyses, drawings, specifications, or materials submitted by the applicant and shall not disclose any principles or patentable features of such equipment, except as required by statute or regulation.

(e) As a condition of each approval issued for any respirator, the Institute reserves the right, following the issuance of such approval, to conduct such public tests and demonstrations of the approved respiratory equipment as is deemed appropriate.

### **§ 84.66 Withdrawal of applications; refund of fees.**

(a) Any applicant may, upon a written request submitted to the Institute, withdraw any application for approval of any respirator.

(b) Upon receipt of a written request for the withdrawal of an application, the Institute shall determine the total man-days expended and the amount due for services already performed dur-

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ing the course of any examinations, inspections, or tests conducted pursuant to such application. The total amount due shall be determined in accordance with the provisions of § 84.22 and assessed against the fees submitted by the applicant. If the total amount assessed is less than the fees submitted, the Institute shall refund the balance together with a statement of the charges made for services rendered.

### **Subpart H—Self-Contained Breathing Apparatus**

#### **§ 84.70 Self-contained breathing apparatus; description.**

(a) Self-contained breathing apparatus, including all completely assembled, portable, self-contained devices designed for use as respiratory protection during entry into and escape from or escape only from hazardous atmospheres, are described as follows:

(1) *Closed-circuit apparatus.* An apparatus of the type in which the exhalation is rebreathed by the wearer after the carbon dioxide has been effectively removed and a suitable oxygen concentration restored from sources composed of:

- (i) Compressed oxygen; or
- (ii) Chemical oxygen; or
- (iii) Liquid-oxygen.

(2) *Open-circuit apparatus.* An apparatus of the following types from which exhalation is vented to the atmosphere and not rebreathed:

(i) *Demand-type apparatus.* An apparatus in which the pressure inside the facepiece in relation to the immediate environment is positive during exhalation and negative during inhalation; or

(ii) *Pressure-demand-type apparatus.* An apparatus in which the pressure inside the facepiece in relation to the immediate environment is positive during both inhalation and exhalation.

(b) The following respirators may be classified as designed and approved for use during emergency entry into a hazardous atmosphere:

(1) A combination respirator which includes a self-contained breathing apparatus; and

(2) A Type “C” or Type “CE” supplied air respirator, where—

(i) The self-contained breathing apparatus is classified for 3-, 5-, or 10-